

In re Patent Application of

Atty Dkt. 1579-804

C# M#

HAYNES et al

TO A.U.

1648

Serial No. 10/664,029

Examiner: Stucker, J.J.

Filed: September 17, 2003

Date: April 8, 2005

Title: IMMUNOGEN COMPRISING AN HIV ENVELOPE PROTEIN, A LIGAND AND H2
PEPTIDE (AS AMENDED)Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.**

Fees are attached as calculated below:

Total effective claims after amendment 0 minus highest number
previously paid for 20 (at least 20) = 0 x \$50.00 \$0.00 (1202)/\$0.00 (2202) \$

Independent claims after amendment 0 minus highest number
previously paid for 3 (at least 3) = 0 x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$

If proper multiple dependent claims now added for first time, (ignore improper); add
\$360.00 (1051)/\$180.00 (2051) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this
paper and attachment(s) One Month Extension \$120.00 (1251)/\$60.00 (2251)

Two Month Extensions \$450.00 (1252)/\$225.00 (2252)

Three Month Extensions \$1020.00 (1253)/\$510.00 (2253)

Four Month Extensions \$1590.00 (1254)/\$795.00 (2254) \$

Terminal disclaimer enclosed, add \$130.00 (1814)/\$65.00 (2814) \$

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) \$ 180.00

Assignment Recording Fee \$40.00 (8021) \$

Other: \$

TOTAL FEE ENCLOSED \$ 180.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

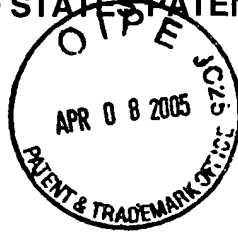
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By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

11/18

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of

HAYNES et al

Serial No. 10/664,029

Filed: September 17, 2003

For: IMMUNOGEN COMPRISING AN HIV ENVELOPE PROTEIN, A LIGAND AND H2 PEPTIDE (AS AMENDED)

Confirmation No. 2598

Atty. Ref.: 1579-804

Group: 1648

Examiner: Stucker, J.J.

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

April 8, 2005

Sir:

INFORMATION DISCLOSURE STATEMENT

- ☐ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits]
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
N/C
- ☒ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of docs on Form PTO-1449 w/copies (where required) of each doc. and translation or concise explanation of non-English docs. (e.g., Search Rpt.) is enclosed (Cruse et al was cited by the Ex. in related Appln. 10/646,729 – a copy is not attached as no copy is in Applicants' file).

This paper is submitted in accordance with:

- ☐ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☒ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier];
and
 - ☐ a) The required Statement made in item 8 below; or
 - ☒ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
 - ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith;
and
 - ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
 - ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
 - ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

HAYNES et al
Serial No. 10/664,029
April 8, 2005

Respectfully submitted,
NIXON & VANDERHYE P.C.

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**INFORMATION DISCLOSURE
CITATION**

(Use several sheets if necessary)

Atty. Docket No.

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1579-804

Applicant

HAYNES et al

Filing Date

Group

September 17, 2003**1648**
U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Furata et al, "Capture of an early fusion-active conformation of HIV-1 gp41", Nature Struct. Biol. 5:276 (1998)
	LaCasse et al, "Fusion-Competent Vaccines" Broad Neutralization of Primary Isolates of HIV", Science 283:357 (1997)
	Boots et al, "Anti-Human Immunodeficiency Virus Type 1 Human Monoclonal Antibodies that Bind Discontinuous Epitopes in the Viral Glycoproteins Can Identify Mimotopes from Recombinant Phage Peptide Display Libraries", AIDS Research and Human Retroviruses 13(18):1549-1559 (1997)
	Bieniasz et al, "HIV-1-induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR-5 co-receptor", The EMBO Journal 16(10):2599-2609 (1997)
	Wild et al, "Propensity for a leucine zipper-like domain of human immunodeficiency virus type 1 gp41 to form oligomers correlates with a role in virus-induced fusion rather than assembly of the glycoprotein complex", Proc. Natl. Acad. Sci. USA 91:12676-12680 (1994)
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	Rizzuto et al, "A Conserved HIV gp120 Glycoprotein Structure Involved in Chemokine Receptor Binding", Science 280:1949-1953 (1998)

*Examiner

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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

INFORMATION DISCLOSURE CITATION

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		5,019,387	5/1991	Haynes et al			
		5,013,548	5/1991	Haynes et al			
		5,352,576	10/1994	Haynes et al			
		5,993,819	11/1999	Haynes et al			
		5,516,632	5/1996	Palker et al			

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS							ABSTRACT	
DOCUMENT			DATE	COUNTRY	CLASS	SUBCLASS	YES	NO
		WO 95/29700	11/1995	PCT				
		WO 97/14436	4/1997	PCT				
		WO 93/15750	8/1993	PCT				
		WO 02/024149	3/2002	PCT				
		WO 01/56355	8/2001	PCT				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

[illegible]

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Form PTO-FB-A820 (Also PTO-1449)

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	Trkola et al, "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1", Journal of Virology 70(2):1100-1108 (1996)
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	Jiang et al, "A Conformation-Specific Monoclonal Antibody Reacting with Fusion-Active gp41 from the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein", Journal of Virology 72(12):10213-10217 (1998)
	Rimsky et al, "Determinants of Human Immunodeficiency Virus Type 1 Resistance to gp41-Derived Inhibitory Peptides", Journal of Virology 72(2):986-993 (1998)
	Earl et al, "Immunogenicity and Protective Efficacy of Oligomeric Human Immunodeficiency Virus Type 1 gp140", Journal of Virology 75(2):645-653 (2001)
	Muster et al, "A conserved neutralizing epitope on gp41 of human immunodeficiency virus type 1", Journal of Virology 67(11):6642-6647 (1993) – Abstract
	Cormier et al, "Specific interaction of CCR5 amino-terminal domain peptides containing sulfotyrosines with HIV-1 envelope glycoprotein gp120", PNAS 97(11):5762-5767 (2000)
	Hoffman et al, "A biosensor assay for studying ligand-membrane receptor interactions: Binding of antibodies and HIV-1 Env to chemokine receptors", PNAS 97(21):11215-11220 (2000)
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	Roben et al, "Recognition properties of a panel of human recombinant Fab fragments to the CD4 binding site of gp120 that show differing abilities to neutralize human immunodeficiency virus type 1", Journal of Virology 68(8):4821-4828 (1994) – Abstract
	Muster et al, "Cross-neutralizing activity against divergent human immunodeficiency virus type 1 isolates induced by the gp41 sequence ELDKWAS", Journal of Virology 68(6):4031-4034 (1994) – Abstract
	Earl et al, "Native oligomeric human immunodeficiency virus type 1 envelope glycoprotein elicits diverse monoclonal antibody reactivities", Journal of Virology 68(5):3015-3026 (1994) – Abstract
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	Fouts et al, "Crosslinked HIV-1 envelope-CD4 receptor complexes elicit broadly cross-reactive neutralizing antibodies in rhesus macaques", PNAS 99(18):11842-11847 (2002)
	Fouts et al, "Expression and Characterization of a Single-Chain Polypeptide Analogue of the Human Immunodeficiency Virus Type 1 gp120-CD4 Receptor Complex", Journal of Virology 74(24):11427-11436 (2000)
	Devico et al, "Monoclonal Antibodies Raised against Covalently Crosslinked Complexes of Human Immunodeficiency Virus Type 1 gp120 and CD4 Receptor Identify a Novel Complex-Dependent Epitope on gp120", Virology 211:583-588 (1995)
	Devico et al, "Covalently Crosslinked Complexes of Human Immunodeficiency Virus Type 1 (HIV-1 gp120 and CD4 Receptor Elicit a Neutralizing Immune Response That Includes Antibodies Selective for Primary Virus Isolates", Virology 218:258-263 (1996)
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DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
WO 94/15638	7/1994	WIPO			
WO 00/08043	2/2000	WIPO			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Devico et al, "Covalently Crosslinked Complexes of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 and CD4 Receptor Elicit a Neutralizing Immune Response That Includes Antibodies Selective for Primary Virus Isolates", <i>Virology</i> 218:258-263 (1996)
	Zhang et al, "Antibody 17b Binding at the Coreceptor Site Weakens the Kinetics of the Interaction of Envelope Glycoprotein gp120 with CD4", <i>Biochemistry</i> 40:1662-1670 (2001)
	Rimsky et al, "Determinants of Human Immunodeficiency Virus Type 1 Resistance of gp41-Derived Inhibitory Peptides", <i>Journal of Virology</i> 72(2):986-993 (1998)
	Zhang et al, "Conformational Changes of gp120 in Epitopes near the CCR5 Binding Site Are Induced by CD4 and a CD4 Miniprotein Mimetic", <i>Biochemistry</i> 38:9405-9416 (1999)
	Liao et al, "Immunogenicity of Constrained Monoclonal Antibody A32-Human Immunodeficiency Virus (HIV) Env gp120 Complexes Compared to That of Recombinant HIV Type 1 gp120 Envelope Glycoproteins", <i>Journal of Virology</i> 78(10):5270-5278 (2004)
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